caDSR 21090 Scope

Document Information
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Contents

Sign off	Date	Role	CBIIT or Stakeholder Organization
Denise Warzel	Draft Oct 21, 2011	Product Manager	
Dianne Reeves		Curator Stakeholder	Community Stakeholder
Sherri De Coronado		Semantic Services V1	CBIIT
Christo Andonyadis		CTMS Stakeholder	Community Stakeholder
Dave Hau		Semantic Infrastructure V2	CBIIT

The **purpose of this document** is to describe the high-level strategy, software development needs and activities surrounding the National Cancer Institute Center for Biomedical Informatics and Information Technology (NCI CBIIT) adoption of **21090 datatypes in caDSR.** This document focuses on the critical features and curation activities that are needed to enable caDSR customers use 21090 Datatypes in their curation activities.

Vision and Needs

The **objective of this project** is to address important usability issues and improve access to information about ISO 21090 Datatypes for caDSR curators in support of customer curation needs.

Current Solution

The Curation Tool supports specifying an ISO 21090 Datatype during curation of 11179 value domains by naming the ISO 21090 type as the ValueDomain.datatype. This documents that the CDE is to be collected using the datatype, but does not provide access to any of the details of the ISO 21090 Datatype. Customers would like for the caDSR to be able to record pertinent details of the 21090 datatypes to support both

informational and operational use cases.

Proposed Solution/Options

The proposed solution is comprised of the following assumptions regarding curation of ISO 21090 template CDEs plus 3 options of varying sophistication and cost relative to storing constant values for specific 21090 datatypes as described in Functional Requirements.

Assumptions:

- ISO 21090 Datatype Templates will be curated by expert curators for use in "Create New from Existing CDE" activities
- Data Element Derivations, (complexType elements composed of the ISO 21090 component data elements) will be used to build the Templates.
- Templates will only be created for concrete datatypes used directly in a data element definition (e.g. HIXT, ANY will not be included since these are Abstract/Parent classes) See NCI CBIIT ISO 21090 Localization Data Type Definitions for list of datatypes that can be used to define data elements.
- A convention for the Representation term for each of the template types will be established and followed by the expert curators
- A naming convention including a specific term such as "Template" as the last term in the template CDE name will be implemented by the expert curators to make the templates easy for curators to find. i.e. "ISO 21090 Data Type Instance Identifier (II) Template"
- Constants will be specified for a Value Domain.
- The CDE Browser will be modified if necessary to display the Value Domain constant values
- The CDE Browser download will be modified if necessary to export the Value Domain constant values
- Component Data Elements will be extended to allow users to specify whether the component is **mandatory, conditional or optional** for the CDE
- Template component data elements that are not used in the 'flavor' can be removed during the "Create New CDE from Existing"
- caDSR Training materials will be modified to teach people how to use the 21090 datatype templates
- Existing Value Domain mechanisms for pointing to external Value Sets will be utilized
- SDTM mapping to BRIDG will be based on BRIDG 3.0.2 DECs through identification and reuse of BRIDG DECs in manual pre-curation activities
- SDTM mapping to 21090 DTs will be able to constrain (remove) or replace 21090 component data elements with equivalent elements but not add new attributes
- SDTM many to one mappings will be handled by creating a Data Element Derivation where the DEC is equal to the mapped DEC and the component CDEs represent the explicit SDTM variables, either by reusing existing caDSR CDEs or by creating new SDTM CDEs
- SDTM one to many mappings will be handled by creating a Data Element Derivation where the component CDEs are the mapped CDEs. In this case the SDTM datatype may not be a 21090 type.
- Form Builder will .....? how to deal with the Derivations in Form builder?

Options for storing ISO 21090 "constants":

Option Name	Description	Curation Tool?	CDE Browser?	Pros	Cons	LOE
A	**Use existing and new caDSR Value Domain attributes to store the ALL constant values.** - This would require an extension to the caDSR data model, as well as to the UIs where the Value Domain details are curated and displayed (Curation Tool, CDE Browser, Sentinnel Tool, possibly Admin Tool). See "Functional Requirements" for the list of constants for each datatype. New attributes are required for: ST.regularExpression, ED.mediaType, PQ.uncertianty, PQ.fixedUnit. These fields will be new attributes that can be specified when curating the Value Domain.	Yes	UI Download	makes each attribute explicit	extends 11179 specifically for 21090	
B	**Use caDSR Alternate names (Designations) to store ALL constant values for each Datatype**, rework the Curation Tool UIs to automatically display the appropriate alternate names fields when an ISO 21090 datatype is selected	Yes	UI Download	consistency in where the 21090 constant values are stored	requires modifications to CDE Browser Value Domain tab to display Alternate Names	
B'	**No changes to the UIs to assist curators with entry of constant values.** Users would click on "Alternate Names" and manually select the alternate name types that match the ISO 21090 datatype.	No	UI Download			

C	**Use a combination of existing Value Domain attributes (low value, high value, min length, max length) and use Alternate Names** for the other fields, rework the Curation Tool UIs to automatically display the appropriate alternate names fields when an ISO 21090 datatype is select	Yes	UI Download	follows current convention for the fields that are already in caDSR for VD	mixed style for collecting the attributes	
C'	No changes to the UIs to assist curators with entry of the constant values. Users would click on "Alternate Names" and manually select the alternate name types that match the ISO 21090 datatyp	No	UI Download			
D	Use a combination of existing Value Domain attributes (low value, high value, min length, max length) and use Reference Docs for the other fields, rework the Curation Tool UIs to automatically display the appropriate Reference Doc types when an ISO 21090 datatype is select	Yes	Download	follows current convention for the fields that are already in caDSR for VD	does not require modifications to CDE Browser Value Domain tab to display Alternate Names, Reference Docs are already displayed	
D'	No changes to the UIs to assist curators with entry of constant values. Users would click on "Reference Documents" and manually select the Reference Docs types that match the ISO 21090 datatype.	No	Download			

Functional Requirements

Each enhancement, modification or new feature is described in detail below.

GForge number (hyperlinked)	Brief description of functional requirement (enhancement or new feature)	Priority	Status (Approved or Proposed)	Benefit	Iteration
	CURATION TOOL				
	Be able to use 24 generic ISO 21090 Datatype "template" from which to begin curation of a new CDE AD (perhaps several for primary countries using the registry), BL, BL.NONULL, CD, DSET, ED, ED.TEXT, EN.TN, EN.ON, EN.PN, II, INT, INT-NonNegative, IVL<INT>, IVL<PQ>, IVL<REAL>, IVL<TS>, PQ, PQ-TIME, REAL, SC, ST, ST.NT, ST.SIMPLE, TS, TEL.PHONE, TEL.URL, TEL.EMAIL, TEL.PERSON, Taken from CDSIC requirements and NCI CBIIT ISO 21090 Localization Data Type Definitions				
	Be able to specify an enumerated Value Domain for the CDE if needed				
	Be able to specify a Value Domain by reference to a external, standard Value Set				
	Be able to specify whether a Data Element Derivation, Component Data Element is Mandatory or Optional or Conditional				
	Be able to specify constant values for: • ST min length, max length and regular expression • ED Media Type • INT min value, max value • PQ min value, max value • PQ Uncertainty • PQ Fixed Unit or Dimension • TS Min time from 'now', Max time from "now"				

	CDE BROWSER				
	Display the details of the CDE's 21090 Datatype in the Browser				
	Display Alternate Names for VD and export the "constant" values (if this approach is used instead of Ref Docs)				
	Display and export the Man/Optional/Conditional indication for each Component Data Element				

Functional Bug Fixes

Each bug fix included in this release is described in detail below.

GForge number (hyperlinked)	Brief description of bug	Priority	Status (Approved or Proposed)	Iteration

Non-Functional Requirements

This section describes in detail all the related requirements which must be met for this release but do not add functionality. These requirements are included in the scope and project plan due to level of effort or relative importance to the overall success of delivery of the release.

GForge number (hyperlinked)	Brief description of non-functional requirement	Status (Approved or Proposed)	Iteration
	Curation of ISO 21090 Datatype Templates		
	Training Materials modified to teach how to use the templates		

General Support Activities

This section describes in detail all the related activities which must be performed for this release but do not add functionality. These activities are included in the scope and project plan due to level of effort or relative importance to the overall success of delivery of the release.

GForge number (hyperlinked)	Brief description of general support activity	Status (Approved or Proposed)	Iteration
	Example, "Level 2 Support, integration of help and training to the user community."		

Stakeholder Summary

Customer Name	Role	Interest/Need
[caDSRproj:Name]	[caDSRproj:Title or role]	

CBIIT Staff/Contractor Name	Role	Responsibilities
[caDSRproj:Name]	[caDSRproj:Role in this project]	

Technical Environment

This product uses the following technical components which have been derived from the current NCICB Technology Stack.

Client Interface	• [caDSRproj:Example, Internet Explorer 6.0 and above] • [caDSRproj:Example, Mozilla v. 1.5.0.3 and above]
Application Server	[caDSRproj:Example, Apache Tomcat 5.5.9]
Database Server	[caDSRproj:Example, Oracle 9i]
Operating System	• [caDSRproj:Example, Windows 2000. XP, Vista] • [caDSRproj:Example, Unix (Sun Solaris)]
[caDSRproj:Other]	

Product Dependencies

This release is dependent on the caCORE components or products documented in the CORE Product Dependency Matrix.

[caDSRproj:Provide additional explanation as applicable. For example, "The EVS vocabulary systems are used by the Java client to retrieve and validate concept information for naming and defining meanings."]

Out of Scope Items

Items that are out of scope were evaluated as part of the initial scoping activities for this release, and subsequently not included in the final approved scope. These items are also documented in the cumulative backlog of requirements found on the product GForge site. They include out-of-scope functional requirements (enhancements or new features), bug fixes, non-functional requirements, and general support activities.

GForge number (hyperlinked)	Brief description of item moved from the in-scope section with brief explanation added of why it was not included in this release	Iteration during which the item was removed from in-scope
https://gforge.nci.nih.gov/tracker/?func=detail&group_id=35&aid=23851&atid=209		

Document History

Document Version:	Click the Info tab. View the Recent Changes or click the link to view the page history.
Last Modified:	Refer to the first line displayed in the document window.
Project GForge site:	[caDSRproj:Project GForge site link]

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Related documents:	[caDSRproj:Name and URL of each related document]

Project Information

CBIIT Management	Role	Responsibilities
Denise Warzel	Product Manager	Oversees development of the product: features, functions, definition of stakeholders, priorities within the scope, timeframe for release
Dave Hau	Engineering Manager	Oversees NCICB caCORE software engineering practices, conducts design reviews, guides technical development